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William J. Thompson
LUBIN & MEYER, P.C.
100 City Hall Plaza
Boston, MA 02108

RE: Estate of Norman Allen

Dear Attorney Thompson,

I am a physician licensed to practice medicine in the state of New York. I am Board Certified in Internal Medicine and Medical Oncology. I am currently an attending Medical Oncologist at New York Presbyterian Hospital in New York, and a Professor of Medicine and Epidemiology at Columbia University's College of Physicians and Surgeons in New York. I am familiar with the accepted standard of care as it pertained to internal medicine physicians caring for patients in Massachusetts from 1998 through the present with regard to the diagnosis and treatment of rectal cancer, as well as to the staging and prognosis of the disease. My curriculum vitae is attached.

At your request, I reviewed the pertinent medical records of Norman Allen, including the office records of Michael Kelly, M.D. dated 2/27/98 to 10/19/99, the office records of Thomas Fazio, M.D. dated 10/4/99 to 11/16/00, the office records of David Farzan, M.D. dated 9/27/99 to 4/5/03 and the death certificate of Norman Allen dated 5/18/02. In addition, I reviewed deposition transcripts of Michael Kelly, M.D., Steven Allen, Tammy Allen, and Ruth Allen.

Norman Allen was a 54-year-old man who died from metastatic rectal cancer on 5/18/02. Mr. Allen's past medical history included a seizure disorder, chronic back and neck pain, a remote history of a benign lung tumor, and question of fibromyalgia. Mr. Allen's family history was positive for rectal cancer in his father.

Mr. Allen was under the care of Dr. Kelly from February 1998 to September 1999. During this time period, colorectal screening was never performed or offered to Mr. Allen by Dr. Kelly despite the fact that Mr. Allen was over 50 years of age. Dr. Kelly testified at his deposition that he understood the standard of care required colorectal cancer screening. In my professional opinion, not offering colorectal cancer screening to Mr. Allen over the age of

50, particularly given the family history of rectal cancer was below the standard of care.

On 4/6/99, at the age of 51 years, Mr. Allen told Dr. Kelly that he was experiencing frequent bowel movements and weight loss. Both weight loss and a change in bowel pattern are symptoms associated with colorectal cancers. However, according to the medical records, Dr. Kelly neither offered nor performed a sigmoidoscopy or colonoscopy to determine the cause of Mr. Allen's change in bowel pattern and weight loss. Furthermore, Dr. Kelly neither offered nor performed colorectal screening in the form of a rectal exam, fecal occult blood testing, sigmoidoscopy with barium enema or colonoscopy in a symptomatic patient over 50 years of age.

On 7/13/99, Mr. Allen followed up with Robert Simms, M.D. for evaluation of his fibromyalgia. Mr. Allen reported to Dr. Simms that he had been experiencing intermittent episodes of bloody stool. Dr. Simms encouraged Mr. Allen to follow-up with Dr. Kelly. Dr. Simms also sent Dr. Kelly a copy of his dictated report that contained reference to Mr. Allen's episodes of bloody stool. As recommended, Mr. Allen followed up with Dr. Kelly on 8/3/99 but there was no reference to Mr. Allen's episodes of bloody stool even though Dr. Kelly noted that he was aware of Mr. Allen's visit with Dr. Simms. Again, Dr. Kelly neither offered nor performed colorectal screening in the form of a rectal exam, fecal occult blood testing, sigmoidoscopy with barium enema or colonoscopy in a symptomatic patient over 50 years of age.

In September of 1999, Mr. Allen switched his healthcare provider to David Farzan, M.D. On 9/27/99, Mr. Allen presented to Dr. Farzan for a physical exam. Dr. Farzan noted Mr. Allen's history of hematochezia (bloody stool) and his family history of rectal cancer. A rectal exam revealed no masses and the hemoccult was negative. Dr. Farzan referred Mr. Allen to Thomas Fazio, M.D., a gastroenterologist, for an evaluation.

On 10/4/99, Mr. Allen presented to Dr. Fazio with complaints of rectal bleeding, frequent bowel movements, a feeling of incomplete bowel movements, alternating diarrhea and constipation, and lower abdominal cramps. Dr. Fazio noted Mr. Allen's family history of rectal cancer and ordered a colonoscopy.

A colonoscopy done on 10/20/99 showed a 3cm mass located at 6cm in the rectum. The mass was biopsied and pathology showed moderately differentiated adenocarcinoma of the rectum. A transrectal ultrasound performed on 11/3/99 showed evidence of invasion and involvement of the muscularis propria. Mr. Allen underwent a surgical low anterior resection for his rectal cancer on 12/1/99. Pathology from the surgical specimen showed lymphatic invasion with one of six lymph nodes positive for metastatic

adenocarcinoma that extended beyond the lymph node capsule. Mr. Allen was diagnosed with a Stage III rectal cancer.

Postoperatively, Mr. Allen received chemotherapy and radiation. Mr. Allen remained in stable condition until April 2002 when extensive liver metastasis was found. On 5/18/02, at the age of 54, Mr. Allen died from metastatic rectal cancer.

DISCUSSION

Based on my familiarity with the natural history of rectal cancer, the patient's prognosis depends largely on the degree of spread at diagnosis. When detected early, rectal cancer is more treatable and more amenable to cure. However, if detected after it has spread beyond the rectum to the lymph nodes, as in Mr. Allen's case, the patient's prognosis is significantly worse.

Early detection and diagnosis of rectal cancer is essential in halting the progression of the disease. For this reason, the accepted standard of care between 1998 and 1999 required the internal medicine physician to perform colorectal cancer screening in the form of a rectal exam, fecal occult blood testing, a barium enema with sigmoidoscopy or a colonoscopy, for persons over 50 years of age.

In my professional opinion, to a reasonable degree of medical certainty, the care and treatment rendered to Norman Allen by Michael Kelly, M.D. from February 1998 to October 1999 fell below the accepted standard of care at the time for the average qualified internal medicine physician when Dr. Kelly failed to perform colorectal screening in the form of a rectal exam, fecal occult blood testing, a barium enema with sigmoidoscopy or a colonoscopy to rule out colorectal cancer in a person over 50 years of age with a family history positive for rectal cancer.

In my professional opinion, to a reasonable degree of medical certainty, the care and treatment rendered to Norman Allen by Dr. Kelly on 4/6/99 fell below the accepted standard of care for the average qualified internal medicine physician when Dr. Kelly failed to offer or perform a sigmoidoscopy or colonoscopy to detect the cause of Mr. Norman's change in bowel pattern and weight loss in a 52-year old male with a family history positive for rectal cancer. In my professional opinion, Dr. Kelly also deviated from the accepted standard of care in August, 1999, when Dr. Kelly neither offered nor performed colorectal cancer screening in the form of a rectal exam, fecal occult blood testing, sigmoidoscopy with barium enema or colonoscopy in a symptomatic patient over 50 years of age with bloody stool.

As a direct result of Dr. Kelly's deviation from the accepted standard of care, the diagnosis and subsequent treatment of Mr. Allen's rectal cancer was significantly delayed, allowing it to grow and spread beyond his rectum to his lymph nodes. Had Dr. Kelly complied with the accepted standard of care, he would have performed a sigmoidoscopy with barium enema or a colonoscopy to completely visualize Mr. Allen's colon and rectum, he would have detected a cancerous lesion earlier than October, 1999, and, more likely than not, Mr. Allen would not have died from metastatic rectal cancer on 5/18/02.

Based on my familiarity with the natural history of colon cancer and given the size, extent, and stage of Mr. Allen's cancer at diagnosis, it is my opinion, to a reasonable degree of medical certainty, that colorectal cancer screening for Mr. Allen would have detected his rectal cancer in a more curable stage.

In conclusion, the care and treatment rendered to Norman Allen by Michael Kelly, M.D. fell below the accepted standard of care at the time for the average qualified physician, significantly increasing the probability of Mr. Allen's death.

Sincerely,

Alfred I. Neugut, M.D., Ph.D.
Professor of Medicine and Epidemiology